

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

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| Date of mailing (day/month/year) 25 July 2001 (25.07.01) | |
| International application No. PCT/US00/27048 | Applicant's or agent's file reference BET-105 PCT |
| International filing date (day/month/year) 29 September 2000 (29.09.00) | Priority date (day/month/year) 05 October 1999 (05.10.99) |
| Applicant LEVIN, Nathan, W. et al | |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 03 May 2001 (03.05.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|----------------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Juan Cruz |
| Facsimile No.: (41-22) 740.14.35 | Telephone No.: (41-22) 338.83.38 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/27048

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 1/00

US CL : 604/29

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/29; 600/382, 384, 547

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-------------------------------------|
| Y | US 5,643,201 A (PEABODY et al.) 01 JULY 1997, See Fig. 1 and related text. | 12,14, 17-20, 23-26, 28-31 |
| Y | US 4,059,169 A (HAGEN) 22 NOVEMBER 1977, See Fig. 1 and related text. | 12,14 17-20 23-26, 28-31 |
| Y | US 3,871,359 A (PACELA) 18 MARCH 1975, See Figs. 1,2 and related text. | 21, 22, 27 29 |



Further documents are listed in the continuation of Box C.



See patent family annex.

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|---|--|
| * Special categories of cited documents: | *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| *A* document defining the general state of the art which is not considered to be of particular relevance | *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| *E* earlier document published on or after the international filing date | *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | *Z* document member of the same patent family |
| *O* document referring to an oral disclosure, use, exhibition or other means | |
| *P* document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

16 DECEMBER 2000

Date of mailing of the international search report

12 JAN 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

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MICHAEL J. HAYES

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PATENT COOPERATION TREATY

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REC'D 07 JAN 2002

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|---|---|--|
| Applicant's or agent's file reference BET-105 PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US00/27048 | International filing date (day/month/year) 29 September 2000 (29.09.2000) | Priority date (day/month/year) 05 October 1999 (05.10.1999) |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 1/00; A61B 5/04, 5/05 and US Cl.: 604/29; 600/384, 547 | | |
| Applicant LEVIN, NATHAN, W. | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input type="checkbox"/> Certain observations on the international application | | |
| Date of submission of the demand 03 May 2001 (03.05.2001) | Date of completion of this report 30 October 2001 (30.10.2001) | |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230 | Authorized officer Michael J. Hayes Telephone No. 703-308-0858 | |

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/27048

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-17 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the claims:
pages 18-27 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the drawings:
pages 1-6 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages None
- ☒ the claims, Nos. None
- ☒ the drawings, sheets/fig None

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/27048

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

| | | |
|-------------------------------|---------------------------------------|-----|
| Novelty (N) | Claims <u>1-39</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>1-11, 13, 15, 16, 32-39</u> | YES |
| | Claims <u>12, 14, 17-31</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-39</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 12, 14, and 17-31 lack an inventive step under PCT Article 33(3) as being obvious over PEABODY in view of HAGEN or PACELA. Peabody discloses a continuous dialysis apparatus as recited in the claims except for controlling the dialysis fluid based on fluid volume in the peritoneal cavity calculated by electrical impedance. Hagen teaches means for readily calculating fluid content of biological volumes via electrical impedance measurements. It would have been obvious to one of ordinary skill in the art at the time of the invention to be obvious to a skilled artisan to use the volume calculation method of Hagen in the system of Peabody to accurately calculate fluid volumes. Pacela discloses a system for measuring impedance including four electrodes, means for measuring voltages between the electrodes, and means to measure volume changes within a patient. Although Pacela does not disclose determining volume in the peritoneal cavity it would be obvious to a skilled artisan to perform such a determination within the peritoneal cavity. Taking the teachings of Pacela and applying them to different areas of the body is within the skill of an ordinary artisan.

Claims 1-11, 13, 15, 16, and 32-39 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest placing measuring electrodes on loins and buttocks, placing upper and lower current-providing electrodes outboard of the measuring electrodes, connecting the electrodes and applying current as claimed to measure voltages to determine volume of fluid in the peritoneal cavity or controlling dialysis fluid composition as claimed in claims 15 and 32 or determining fluid conductivity as claimed in claims 16 and 33.

----- NEW CITATIONS -----